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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/844,662	04/27/2001	Eva Raschke	8325-0012	9004
20855	7590	03/24/2006	EXAMINER	
ROBINS & PASTERNAK 1731 EMBARCADERO ROAD SUITE 230 PALO ALTO, CA 94303			BRUSCA, JOHN S	
			ART UNIT	PAPER NUMBER
			1631	

DATE MAILED: 03/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/844,662

Applicant(s)

RASCHKE ET AL.

Examiner

John S. Brusca

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 27 December 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 57,63,64,66,68-71 and 87-90 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 57,63,64,66,68-71 and 87-90 is/are rejected.
- 7) ☒ Claim(s) 68 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |                                                                                                                        |                                                                                         |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                            | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____                                                |

### **DETAILED ACTION**

1. This application has been transferred to a new art unit and a new examiner.

#### ***Specification***

2. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code on page 15. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

3. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR §§ 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR §§ 1.821-1.825 for the following reasons:

Several nucleotide sequences appear in the specification on pages 28, lines 6-7 that are not properly identified. Nucleotide sequences must be identified by sequence identification number. Furthermore, if said sequences do not appear in the sequence listing, a new listing including said sequences must be supplied. It is often convenient to identify sequences in figures by amending the Brief Description of the Drawings section (see MPEP 2422.02). If said sequences consist of a portion of sequences already of record in the sequence listing, they may be identified in the specification using the existing SEQ ID No. accompanied by the position of the sequence on the already listed sequence.

Applicants are required to comply with all the requirements of 37 CFR §§ 1.821-1.825. Any response to this Office Action which fails to meet all of these requirements will be considered non-responsive. The nature of the sequences disclosed in the instant application has allowed an examination on the merits, the results of which are communicated below.

***Claim Objections***

4. Claim 68 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 68 depends from cancelled claim 67. For the purpose of examination claim 68 has been assumed to depend from claim 66.

***Claim Rejections - 35 USC § 102***

5. The rejection of claims 57, 62-68, 70 and 71 under 35 U.S.C. 102(e) as being anticipated by Cox, III et al. in the Office action mailed 23 September 2005 is withdrawn in view of the arguments presented on pages 4-6 and the cancellation of claims 62, 65, and 67 filed 27 December 2005.

6. The rejection of claim 60 under 35 U.S.C. 102(e) as being clearly anticipated by Cox, III et al. as evidenced by Neely et al. in the Office action mailed 23 September 2005 is withdrawn in view of the cancellation of claim 62 filed 27 December 2005.

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 57, 63, 64, 66, 68, 70, 88, and 89 are rejected under 35 U.S.C. 102(b) as being anticipated by Crossley et al. in light of Chen et al. and Morceau.

The claims are drawn to a complex of an exogenous polypeptide bound to cellular chromatin. The binding site is sensitive to a probe of chromatin structure. In some embodiments

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the exogenous polypeptide is a zinc finger transcription factor and the probe is DNase I. In some embodiments the claims are drawn to an animal cell comprising the complex, and the exogenous polypeptide is encoded by a polynucleotide introduced into the cell.

Crossley et al. shows in the introduction that the erythroid Kruppel-like factor (EKLF) gene encodes a transcription factor related to globin expression. Crossley et al. shows that the promoter contains a GATA-1 binding site, and that GATA-1 activates the EKLF promoter on page 15441 and figures 2, 4, and 5. Crossley et al. shows transactivation of an EKLF promoter in mouse NIH3T3 cells by introduction of a polynucleotide expression vector that expresses GATA-1 in page 15442 and figure 6.

Chen et al. shows that an inherent property of the chromatin structure of an EKLF promoter in a cell is that it comprises two DNase I hypersensitive sites, and that the distal site comprises the GATA-1 binding site in figures 1-3, which is summarized in the model in figure 10.

Morceau et al. reviews GATA-1, and shows that it is a zinc finger protein on page 537, 542-543, and figure 1.

### ***Claim Rejections - 35 USC § 103***

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various

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claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 57, 66, and 71 are rejected under 35 U.S.C. 103(a) as being unpatentable over Crossley et al. in view of Chen et al.

The claims are drawn to a complex of an exogenous polypeptide bound to cellular chromatin. The binding site is sensitive to a probe of chromatin structure. In some embodiments the claims are drawn to a human cell comprising the complex.

Crossley et al. shows in the introduction that the erythroid Kruppel-like factor (EKLF) gene encodes a transcription factor related to globin expression. Crossley et al. shows that the promoter contains a GATA-1 binding site, and that GATA-1 activates the EKLF promoter on page 15441 and figures 2, 4, and 5. Crossley et al. shows transactivation of an EKLF promoter in mouse NIH3T3 cells by introduction of a polynucleotide expression vector that expresses GATA-1 in page 15442 and figure 6.

Chen et al. shows that the chromatin structure of an EKLF promoter in a cell comprises two DNase I hypersensitive sites, and that the distal site comprises the GATA-1 binding site in figures 1-3, which is summarized in the model in figure 10. Chen et al. shows the human EKLF promoter gene and the mouse EKLF gene are highly conserved in figure 2.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the complex of Crossley et al. by substitution of the human EKLF

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gene of Chen et al. because Chen et al. shows the two genes are highly conserved and the substitution would allow for further research on transcriptional control of the human EKLF gene.

12. Claims 57, 66, and 87 are rejected under 35 U.S.C. 103(a) as being unpatentable over Crossley et al. in view of Chen et al. as applied to claims 57, 66, and 71 above, and further in view of Hays (reference AO-1 in the Information Disclosure Statement filed 10 May 2004).

The claims are drawn to a complex of an exogenous polypeptide bound to cellular chromatin. The binding site is sensitive to a chemical probe of chromatin structure.

Crossley et al. in view of Chen et al. as applied to claims 57, 66, and 71 above does not show determination of chromatin structure by use of a chemical probe.

Hayes reviews the use of chemical probes to analyze chromatin structure.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the complex of Crossley et al. in view of Chen et al. as applied to claims 57, 66, and 71 above by use of chemical probes because Hayes shows that chemical probes are effective means to analyze chromatin structure.

13. Claims 57, 66, and 90 are rejected under 35 U.S.C. 103(a) as being unpatentable over Crossley et al. in view of Chen et al. as applied to claims 57, 66, and 71 above, and further in view of Gregory.

The claims are drawn to a complex of an exogenous polypeptide bound to cellular chromatin. The binding site is sensitive to a restriction endonuclease probe of chromatin structure.

Crossley et al. in view of Chen et al. as applied to claims 57, 66, and 71 above does not show determination of chromatin structure by use of a restriction endonuclease probe.

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Gregory reviews the use of restriction endonucleases as probes to analyze chromatin structure.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the complex of Crossley et al. in view of Chen et al. as applied to claims 57, 66, and 71 above by use of restriction endonuclease probes because Gregory shows that restriction endonuclease probes are effective means to analyze chromatin structure.

14. Claims 57, 66, and 69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Crossley et al. in view of Chen et al. as applied to claims 57, 66, and 71 above, and further in view of Greisman et al. (reference AN-1 in the Information Disclosure Statement filed 10 May 2002).

The claims are drawn to a complex of an exogenous polypeptide bound to cellular chromatin. The binding site is sensitive to a restriction endonuclease probe of chromatin structure. In some embodiments the claims are drawn to a plant cell comprising the complex.

Crossley et al. in view of Chen et al. as applied to claims 57, 66, and 71 above does not show plant cells comprising exogenous polypeptides bound to chromatin.

Greisman et al. teach a strategy for selecting high-affinity zinc finger proteins for diverse DNA target sites. Greisman et al. shows a strategy for selecting high-affinity zinc finger proteins for diverse DNA target sites. Additionally, at column 7, lines 29-30, they state that the zinc finger proteins provide means for developing plants with altered phenotypes.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the complex of Crossley et al. in view of Chen et al. as applied to



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claims 57, 66, and 71 above by use of a complex of a zinc finger protein with chromatin in a plant cell in view of the conventionality of doing so taught by Greisman et al.

### ***Conclusion***

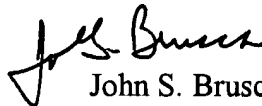
15. Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center at (800) 786-9199. Any inquiry concerning this communication or earlier communications from the examiner should be directed to John S. Brusca whose telephone number is 571 272-0714. The examiner can normally be reached on M-F 8:30 AM - 5:00 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, PhD. can be reached on 571 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

 19 March 2006

John S. Brusca  
Primary Examiner  
Art Unit 1631

jsb